UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

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DATE MAILED: 02/25/2008

# NOTICE OF ALLOWANCE AND FEE(S) DUE

20311 7590 0225/2008 LUCAS & MERCANTI, LLP 475 PARK AVENUE SOUTH 15TH FLOOR NEW YORK NY 10016 EXAMINER

ARNOLD, ERNST V

ART UNIT PAPER NUMBER

1616

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/528,749	03/22/2005	In-San Kim	428.1051	8173	

TITLE OF INVENTION: BONE-FILLING COMPOSITION FOR STIMULATING BONE-FORMING AND BONE-CONSOLIDATION COMPRISING CALCIUM SULFATE AND VISCOUS BIOPOLYMERS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$720	\$300	\$0	\$1020	05/27/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THE APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FFE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This appropriate. All further e indicated unless correcte maintenance fee notificat	form should be used I correspondence including d below or directed off ions.	or tran ig the l icrwise	smitting the ISSU Patent, advance or in Block 1, by (a	ders and notification a) specifying a new co	of m	naintenance fees w pondence address;	ill be and/or	nailed to the current (b) indicating a sepa	corres rate "I	pondence address as FEE ADDRESS" for
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										(Date)
APPLICATION NO. FILING DATE			FIRST NAMED INVENTOR			ATTORNEY DOCKET NO. CONFIRMA			FIRMATION NO.	
10/528,749	03/22/2005			In-San Kim				428.1051		8173
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APPLN. TYPE	SMALL ENTITY	IS:	SUE FEE DUE	PUBLICATION FEE D	UE	PREV. PAID ISSUE FEE TOTAL FEE(		TOTAL FEE(S) DUE		DATE DUE
nonprovisional	YES		\$720	\$300		\$0		\$1020		05/27/2008
EXAM	INER		ART UNIT	CLASS-SUBCLASS						
ARNOLD,	ERNST V		1616	424-426000	_					
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NOTE: The Issue Fee and interest as shown by the r	f Publication Fee (if req ecords of the United Sta	uired) v tes Pate	will not be accepted ent and Trademark	d from anyone other the Office.	an th	ne applicant; a regi	stered a	ttorney or agent; or th	e assış	ince or other party in
Authorized Signature						Date				
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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



# UNITED STATES PATENT AND TRADEMARK OFFICE

#### UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

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20311	7590 02/25/2008		EXAMINER			
LUCAS & MEF	RCANTI, LLP	ARNOLD, ERNST V				
475 PARK AVEN	VUE SOUTH		ART UNIT	PAPER NUMBER		
15TH FLOOR NEW YORK, NY 10016			1616 DATE MAILED: 02/25/2008			

# Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

# Notice of Allowability

Application No.	Applicant(s)		
10/528,749	KIM ET AL.		
Examiner	Art Unit		
FRNST V ARNOLD	1616		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative

- of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.
- This communication is responsive to 12/3/07.
- The allowed claim(s) is/are 1, 3-5, 7 and 8 frenumbered as 1-6].
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - b) ☐ Some\* c) ☐ None of the: a) 🔯 All
    - 1. A Certified copies of the priority documents have been received.
    - 2. Certified copies of the priority documents have been received in Application No.
      - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) hereto or 2) to Paper No./Mail Date
  - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. 

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- 1. | Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08). Paper No./Mail Date
- 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. T Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- Other .

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### DETAILED ACTION

Claims 1, 3-5, 7 and 8 are pending.

# Response to Amendment

The Declaration under 37 CFR 1.132 filed 12/3/07 is sufficient to overcome the rejection of claims 1, 5 and 8 based upon 35 U.S.C. 103(a) as being unpatentable over Liu (US 5,281,265) in view of Petersen et al. (US 2002/0071827 Pub. Date: 06/13/2002) and Zimmermann (US 6,692,563) and Walker (US 4,795,475) and claims 1, 3, 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al. (US 2002/0071827 Pub. Date: 06/13/2002) in view of Liu (US 5,281,265) and Zimmermann (US 6,692,563) and Walker (US 4,795,475). Applicant has clearly shown a difference in kind rather than a difference in degree with respect to the alkaline phosphatase assay which is indicative of the osteoinductive effect of the composition. The rejections are withdrawn by the Examiner.

The following is an examiner's statement of reasons for allowance: Applicant has shown in the 1.132 Declaration about a 40% enhanced alkaline phosphatase activity with the instant invention over the composition taught by Petersen et al. As is clearly shown in Table 2 of the Declaration (page 8), the inventive composition resulted in about 100 nmol/min/µg alkaline phosaphatase activity while the prior art composition resulted in only about 71 nmol/min/µg alkaline phosaphatase activity. This significant

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and unexpected difference between the prior art and the instant invention is deemed to be a difference in kind and would have been unobvious to one of ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

# Allowable Subject Matter

Claims 1, 3-5, 7 and 8 [renumbered as 1-6] are allowed.

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Amold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold Patent Examiner Technology Center 1600 Art Unit 1616

Supervisory Patent Examiner, Art Unit 1616

\_\_/Johann R. Richter/

Johann R. Richter Supervisory Patent Examiner Technology Center 1600